DETAILED ACTION

This office action is in response to claims filed 7/21/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed application does not include "a distal shaft ...consisting of a single layer".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 3, 6, 7, 11, 27, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al. (US 6.036670) in view of Berg et al. (US 5911715).

Wijeratne teaches a catheter comprising the following:

- a proximal shaft (32)
- an intermediate member (distal end of 32, Fig. 2) connected to a front side of said proximal shaft (where 23 passes through 32 and 22 in Fig. 2)
- a distal shaft (22) connected to a front portion of said intermediate shaft (where 38 touches 37 in Fig. 2)
- a hub (34) provided to a rear side of said proximal shaft
- a balloon (21) provided at a front portion of said distal shaft
- an inner tube shaft (23) coaxially extends through said distal shaft and said balloon and connected at a distal end of said balloon (fig. 1)
- a balloon lumen for communicating said hub to the inside of said balloon
- a guide wire lumen (23) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (25) positioned on the distal side from a front end of said balloon and a proximal side aperture (26) formed in a side surface of said intermediate member (Figs. 2 and 5, the side surface of the intermediate member forms the aperture).

Wijeratne fails to teach the following:

- wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft is configured as a grooved portion having a groove

- said grooved portion has a distal end locate near a connection portion between said balloon and said distal shaft and a proximal end located toward a distal side of said proximal side aperture
- wherein said groove is formed into spiral shape or annular shape.
- wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter.
- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the depth of said groove is changed in the direction toward the distal end of said catheter.
- wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region.
- wherein said grooved portion is provided at a portion adjacent to said balloon.
- wherein said groove is formed in an outer surface of said distal shaft.
- said groove possessing a depth which changes relative to a longitudinal extent of the distal shaft so as to be relatively larger on a distal side of said grooved portion and relatively smaller on a proximal side of said grooved portion.

Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), said grooved portion has a distal end locate near a connection portion (it is noted that the term near is broad and may encompass a location anywhere along the device, and further a connection portion may simply be the transition between balloon and the distal shaft portion) between said balloon and said distal shaft a proximal end located toward a distal side of said proximal side aperture (Fig. 9), wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 11 c) and wherein said groove is formed in an outer surface of said distal shaft (fig. 9) in order to provide a device having increased flexibility for better maneuverability. Berg teaches said groove possessing a depth which chanqes relative to a longitudinal extent of the distal shaft (Fig. 11) so as to be relatively larger on a distal side of said grooved portion and relatively smaller on a proximal side of said grooved portion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wijeratne with the grooved portion as taught

by Berg in order to provide a device having increased flexibility for better maneuverability.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al. (US 6.036670) and Berg (US 5911715), as applied to claim 1 above, and further in view of Keith (US 5217482).

Wijeratne and Berg teach the claimed invention, but are silent regarding the hardness of the distal shaft, however Keith teaches a catheter comprising the following:

- wherein said distal shaft is made from a polymer material having a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cmz or more (Column 7, proximate lines 34-36). Keith teaches wherein the distal shaft is formed of a high-density polyethylene, which inherently has a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm2.
- wherein said distal shaft has a distal portion (34) and a proximal portion (110), and the rigidity of said proximal portion (110) of said distal shaft is lower than that of said proximal shaft (22) and is higher than that of said distal portion (34) of said distal shaft (Column 9, proximate lines 1-10).

It would have been obvious to one of ordinary skill in the art to use the material of Keith the invention of Wijeratne and Berg, as HDPE (high density polyethylene) is a commonly used material in the art, and has been proven successful.

Claims 4, 9, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wijeratne and Berg, as applied to claim 1, and further in view of Keith and as a matter of design choice.

The combination of Wijeratne, Berg and Keith teach all of the limitations of preceding dependent claims 1 and 12 as previously disclosed, but fails to describe the following:

- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more.

Regarding the limitations wherein the groove is in a range of 30 to 90% of the wall thickness of said distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more, the combination of Wijeratne, Berg and Keith teach a device wherein the grooves are in place in order to provide a smooth transition from the proximal rigid portion to the more flexible distal portion (Berg), but does not teach the exact depth of the grooves in relation the thickness of the shaft. It appears that the combination of Wijeratne, Berg and Keith performs the task of providing a smooth transition from the proximal rigid portion to the more flexible distal portion equally well as that disclosed in the application. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose make the depth of

the groove in a range of 30 to 90% of.the wall thickness of the distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 10/30/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Berg teaches away from increasing the flexibility of the distal section of the catheter

The examiner respectfully disagrees with the applicant, Berg teaches that flexibility is necessary (col. 2, ll. 34-46). The applicant's argument regarding the rejection of claim 1 as being unpatentable over Keith in view of Berg is persuasive, the amendments overcome this previous rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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